

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 3, 2019

Catherine Rice Agent for North American Infection Control, Ltd. c/o Steptoe & Johnson 1330 Connecticut Avenue NW Washington, D.C. 20036

Subject: Label Notification per PRN 98-10– Add Optional Language to the Master Label.

Notification to Add Optional Descriptions of Use Existing Use Site and Types of

Surfaces to the Master Label. Product Name: Peak Disinfectant EPA Registration Number: 88494-3 Application Date: February 15, 2019

Decision Number: 549160

Dear Ms. Rice:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Srinivas Gowda by phone at 703-308-6354, or via email at gowda.srinivas@epa.gov.

Sincerely,

Sounda for Jacqueline Hardy

Product Manager – Team 34 Regulatory Management Branch II

Antimicrobials Division (7510P)

## **Peak Disinfectant**

#### NOTIFICATION

88494-3

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

05/03/2019

ACTIVE INGREDIENTS:	
Ethyl Alcohol	72.50%
Didecyl Dimethyl Ammonium Chloride	0.33%
OTHER INGREDIENTS	27.17%
Total	100.00%

# Keep Out of Reach of Children CAUTION

See [back] [side] panel for additional precautionary statements

EPA Reg. No. 88494-3 EPA Est. No. XXXXX-XX-X

[Made] [Manufactured] for:

North American Infection Control Ltd.
209 Strathearn Road
Toronto, Ontario M6C1S5 Canada

NET CONTENTS: X lbs. X ozs. [1 gallon] [1 quart] [1L] [1 pint] [500 ml] [8 oz] [220 ml]

[EFFECTIVE] [WORKS] [KILLS BACTERIA/FUNGI/VIRUSES\*] [IN ONE MINUTE/60 SECONDS]

[ONE MINUTE] [CLEAN AND DISINFECT] [ONE STEP] [ONE PRODUCT] [ONE SOLUTION] [NEW] [EASY][EFFECTIVE][FAST AND EFFECTIVE] [CONVENIENT]

[CLEANS, DISINFECTS & DEODORIZES]

[ALL PURPOSE] [CLEANER] [DEODORIZER] [DETERGENT] [DISINFECTANT] [ANTIBACTERIAL] [DETERGENT] FORMULA CLEANS [and] DISINFECTS and DEODORIZES]

[UNSCENTED] [FRAGRANCE FREE]

[BLEACH-FREE]

[BACTERICIDAL] [TUBERCULOCIDAL] [FUNGICIDAL] [VIRUCIDAL\*]

[Kills Viruses\* Most [Responsible for] [Associated with] the Common Cold]

[Kills Antibiotic Resistant Bacteria CRE, MRSA, VISA, VRSA, and VRE]

[Effective Against] [Kills] [the] [ESKAPE Pathogens] [Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter species] [which are responsible for a substantial proportion of nosocomial infections in hospitals, and represent the vast majority of isolates whose resistance to antimicrobial agents presents serious therapeutic concerns for the medical community.] [Kills Flu Virus\*]

[Kills Pandemic 2009 H1N1 Influenza A virus\*] [formerly called swine flu]

- [Antibacterial] [Disinfecting] and scrubbing power all in one
- 99.99% effective in killing common [household] [bathroom] bacteria
- Antibacterial [detergent] formula cleans and disinfects in one step
- [Antimicrobial] [Antibacterial] Spray
- [Clean] and [Disinfect] hard, non-porous surfaces
- [Clean] and [Disinfect] [patient and] public areas in [hospitals] [medical offices] [dental offices] [ambulatory care facilities] [veterinary offices] [nursing homes] [long term care facilities] [ambulances] [residential sick rooms] [mortuaries] [pet shops] [animal holding areas] [pet grooming facilities]
- Cleaning made easy for all your hard, non-porous surfaces
- Cleans and cuts grease
- Cleans tough stains
- Cleans, [disinfects] and deodorizes
- Cuts through tough grime
- Easy Cleaning
- Easy to use
- Effective against odor-causing bacteria
- Effective daily use
- Effective in [disinfecting] [your] [the] [bathroom] [Medical] [Dental] [Veterinary] [Ambulance] [Emergency Vehicle] [Institutional] [pet care] [surfaces]
- Eliminates odors
- Fast and easy way to clean
- Fast and effective cleaning
- For all non-porous [environmental] surfaces
- For all your [heavy] [light] duty jobs
- Ideal for cleaning and [disinfecting] hard, non-porous surfaces

- Kills common [institutional] [bathroom] bacteria
- Fragrance Free
- Leaves [your] [the] [bathroom] [institution] [facility] fresh and clean
- One-step [clean] [cleaning] and [disinfect] [disinfection]
- Quick cleaning
- Saves time
- Use every day in every room [throughout the facility] [throughout the institution]
   [throughout the office]
- Use in [public toilets] [Laundromats] [pet areas] [hotels] [motels] [lodging establishments]
   [manufacturing facilities] [factories] [offices] [office buildings] wherever [disinfecting]
   [disinfection] is important
- Use on hard, non-porous surfaces: [stainless steel] [Formica®] [glass] [glass tables]
   [glazed porcelain] [plastic] [quartz] [sealed stone] [other hard and soft metals] [most painted surfaces] [most plastics] [see elsewhere on label for further guidance]
- [This product or product name] cleans and/or disinfects and/or deodorizes.
- [Antibacterial] [Disinfectant] [Detergent] [formula] [Cleans and] Disinfects in [just]
   1 minute.
- Leaves hard, non-porous surfaces disinfected.
- One step [cleaning] and /or [disinfecting] and/or [deodorizing]
- [Disinfectant] [Disinfecting] [spray] for hard, non-porous surfaces, [patient care equipment] [and] [point-of-care-equipment]
- Meets [OSHA Bloodborne Pathogen Standard] [AHE Practice Guidance for environmental cleaning] [CDC Guidelines for Disinfection and Sterilization in Healthcare] [CDC Guidelines for Infection Control in Dental Health-Care Settings] [CDC Infection Prevention & Control in Dental Settings]

### [Optional text for Use Sites]:

[May be used on hard non-porous surfaces of] {surfaces will be selected from the following} autoclaves, bed railings, blood glucose monitors, Biological Safety Cabinets (BSCs), Biosafety Cabinets (BSCs), Restricted Access Barrier Systems (RABS), Closed Restricted Access Barrier Systems (C-RABS), Mobile Cleanrooms, Half Suit Isolators, cabinets, (cleanroom) carts, chairs, closets, controlled environments, counters, countertops, desks, exam tables, exteriors of (refrigerators)(freezers), furniture, garbage cans, glove boxes, gurneys, Isolator Hood surfaces, isolates, infant incubators and care cribs, IV poles, operation tables, pass through doors, door handles, doorknobs, patient room beds, phlebotomy trays, Primary Engineering Controls (PECs), PVC tubing, recycling bins, Secondary Engineering Controls (SECs), sterile compounding hoods, stethoscopes, stretchers, tables, bathrooms, sinks, faucets, toilet seats [and rims], towel dispensers, hand railings, lamps, light switch panels, stall doors, bath tubs, showers, hampers, tiled walls, telephones, door knobs, vanities, non-porous shelves, display cases, walls, [and] work surfaces.

[This product or product name] is intended for use in:

- Hospitals and healthcare settings, including: Ambulances, Anesthesia, CAT Labs, CCU, Central Supply, Clinics, Dental Offices, Dialysis Clinics, Doctor's Office[s], Emergency Rooms, [E.R.], Home Health Care, Hospices, Laboratory, Laundry Rooms, Long Term Care Facilities, Newborn Nursery, Nursing Homes, Offices, Operating rooms, Pediatrics, Physical Therapy, Physician's Office[s], Ophthalmic Offices, Radiology, Recovery Room, Rehabilitation, Respiratory Therapy, Ultrasound, Transport Vehicles, Waiting Areas, X-Ray.
- Critical Care Areas: [CCU] Cardiac Care Units, [E.R.] Emergency Rooms, [ICU] Intensive Care Units, , [NICU] Neonatal Intensive Care Units, [PICU] Pediatric Intensive care Units, Surgery, Surgical Prep, and Surgical Recovery Units.
- Barber Shops, Beauty Salons, Correctional Facilities, Funeral Homes, Mortuaries.
- Airports, Athletic Facilities, [Gyms] Gymnasiums, Health Clubs, Schools, Transportation Terminals.
- Banquet Halls, Catering Facilities, Delicatessens, Grocery stores, Shopping Centers, Restaurants.
- Childcare Facilities, Daycare Centers, Nurseries.
- Households, Homes, Residences, and/or Bathrooms.
- Institutional Bathrooms [Restrooms] [Toilet Facilities].
- Animal Housing/Holding Facilities [Areas]
- Animal Hospitals, Animal Life Science Laboratories, Animal Transportation Vehicles, Breeding Establishments, Grooming Establishments, Kennels, Pet Shops, Tack Shops, Veterinary Clinics, Veterinary Examination Rooms, Veterinary Operating Rooms, Veterinary Waiting Rooms, Veterinary X-Ray Rooms, Zoos.

## [Optional Areas of Use/Industries]

[Disinfectant for use on hard, non-porous surfaces in:] {optional sites will be selected from the following} Animal Life Science Laboratories, Bathrooms, Churches, [ISO Class (number)] Cleanrooms, (Sterile) Compounding Facilities, Clinics, Colleges, Cosmetic Processing Facilities, Critical Care Units, Cruise Ships, Dialysis Centers, Funeral Homes, Dental Offices, Health Clubs, Hospices, Hospitality Establishments, Hospitals, Home Health Care, Hotels, Industrial Facilities, Institutions, Laboratories, Nail Salons, Nursing Homes, Medical Device Manufacturing, Morgues, Office Buildings, Oncology Centers, Outpatient Centers, Pharmaceutical Production Facilities, Pharmacies, Physical Therapy Locations, Physicians' Offices, Public Facilities, Radiology, Recreational Facilities, Rehabilitation Centers, Research Laboratories, Retail and Wholesale Establishments, Shelters, Storage Areas, Surgery Centers, Locker Rooms, Long-Term Care Facilities, The interior areas of the following Transport Vehicles: including ships, airplanes, automobiles, trucks, ambulances, and trains.

When Animal Housing/Holding Facilities are included on the label, the following directions must be added:

## **Veterinary Clinics, Animal Life Science Laboratories, Pet Shops**

Remove all animals and feed from premises, vehicles, and enclosures. Remove all litter and manure from floors, walls, and surfaces of facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Wet surfaces for 1 minute. Immerse all handling and restraining equipment as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, vehicles, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub treated feed troughs, racks and other feeding and watering appliances with soap or detergent, then rinse with potable water before reuse.

- [This product or product name] will clean and disinfect hard, non-porous, surfaces of: bed railings, cabinets, carts, chairs, counters, infant incubators, infant warmers, Isolettes, IV poles, IV pumps, stretchers, stools, tables, toilet seats, toilets, bathtubs, bathroom fixtures, shower stalls, sinks, tiles, vanity tops, hospital beds, traction devices, MRI, CAT, scales, paddles, and workstations on wheels (WOW).
- [This product or product name] can be used to clean [and decontaminate] external surfaces of ultrasound transducers and probes, prior to any required high level disinfection or sterilization. It is recommended that any gel and gel residue be thoroughly removed before disinfection with this product.
- [This product or product name] can be used to disinfect EKG cables, leads, clips, plate electrodes, welsh cups and bulbs, and straps. It is recommended that any gel and gel residue be thoroughly removed before disinfection with this product.
- [This product or product name] will clean and disinfect the outside surfaces of blood glucose meters, PT/INR meters, and similar diagnostic instruments and measuring devices.
- [This product or product name] will clean and disinfect blood pressure cuffs, cardiac gym equipment, cardiac monitors, defibrillators, dopplers, oxygen hoods, physical therapy (PT) and occupational therapy (OT) equipment surfaces, patient lift equipment, slit lamps, spine back boards, stethoscopes, telemetry equipment, telephones, toilet seats, and hard nonporous outside surfaces of anesthesia machines, dialyzers, electronic thermometers, Ophthalmoscopes, Otoscopes, pulse oximeters, radiology equipment, tympanic thermometers, respiratory therapy equipment, apheresis machines, diagnostic equipment, dialysis machines, patient monitoring equipment, patent support and delivery equipment, pulp testers, and motors.
- [This product or product name] will clean and disinfect dental unit instrument trays, endodontic equipment such as apex locators, and hard outside nonporous surfaces of amalgamators and dental curing lights.
- [This product or product name] will clean and decontaminate hard outside nonporous surfaces of dental instruments that are not required to be treated with a high level disinfectant or sterilant.
- [This product or product name] will clean and disinfect hard, non-porous, surfaces of: [exam tables, gurneys, stretchers, wheel chairs, and patient transport chairs], [and vinyl or nylon covered mattresses] [or other nonporous upholstered materials such as blood bank chairs, and dental chairs]. When using [this product or product name] on chairs, mattresses, or other upholstered surfaces or materials that had previously been treated with a product containing a higher percentage of quaternary ammonium compounds, or bleach, it is recommended that the surface be thoroughly cleaned with an alcohol based cleaner, or in accordance with the upholstery material manufacturer's recommendations or directions to remove any built-up residue from the previously used product, before applying this product.
- [This product or product name] will clean and disinfect hard, non-porous surfaces of: grocery cart handles, grocery carts, shopping carts, grocery cart child seats.
- [This product or product name] will clean and disinfect hard, non-porous surfaces of: changing tables, cribs, diaper pails, trashcans, garbage cans.
- [This product or product name] will clean and disinfect hard, non-porous surfaces of: cabinets, chairs, computers, countertops, desks, desktops, doorknobs, fax machines, garbage cans, headsets, keyboards, railings, seats, sinks, tables, tabletops, telephones, trashcans, appliance exteriors, [bathroom] faucets, bathtubs, and shower [doors][stalls].

- [This product or product name] will clean and disinfect hard, non-porous surfaces of: gym equipment, exercise machines, non-porous wrestling/gymnastic/exercise/yoga mats, gymnastic [athletic] equipment.
- Use [this product or product name] to clean and disinfect non-porous personal protective safety equipment, protective headgear, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, silicone rubber or PVC hearing protectors and vinyl covered ear muffs. Rinse all equipment that comes in prolonged contact with skin before reuse with clean warm water [about 120°F], and allow to air dry. [Caution: Cleaning at the 120°F temperature will avoid overheating and distortion of the personal safety equipment that would necessitate replacement.]
- [This product or product name] is formulated to disinfect hard, non-porous, inanimate environmental surfaces such as floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, and cabinets.
- [This product or product name] helps prevent cross contamination from contact with treated surfaces.
- [This product or product name] [can be used as a] disinfectant for hard non-porous surfaces, [patient care equipment] [and] [point-of-care equipment]
- [This product or product name] will clean and disinfect hard nonporous surfaces found in Nursery or Daycare Centers, including but not limited to bassinets, changing tables, cribs, diaper changing stations, diaper pails, infant/child care equipment surfaces, trash cans, toys and other such surfaces found elsewhere on this label.

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For labels that list medical premises one of the following statements must be used:

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

Of

This product is not for use on critical and semi-critical medical device surfaces.

**CLEANING:** Wet surface sufficiently and clean with a mop, sponge, cloth, nonwoven wipe, or other suitable cleaning instrument to thoroughly clean the surface.

**DISINFECTING:** To disinfect hard, non-porous surfaces, spray product as necessary, to thoroughly wet the surface to be treated. Treated surface must remain visibly wet for one [1] minute to achieve complete disinfection [or kill] of all pathogens listed on this label. For visibly soiled surfaces, clean before following disinfecting instructions. Allow surfaces to air dry.

Optional additional use statements that may be used

[For use as a cleaning and pre-decontaminant immersion solution: Place instruments in a container with a sufficient amount of [this product or product name] so as to allow for complete submersion, cover and immerse at room temperature (68 °F/20 °C) until ready for disinfection or sterilization. Remove and rinse instruments. Follow with appropriate disinfection or sterilization process. Discard solution after each use.]

[For use as a cleaning and pre-decontaminant spray: Place instruments in a container. Spray [this product or product name] so as to thoroughly drench all instrument surfaces and allow to remain visibly wet for 1 minute. Remove and rinse instruments. Follow with appropriate disinfection or sterilization process.]

[For use as an ultrasonic cleaning solution: Thoroughly rinse instruments under running water to remove visible gross debris. Add [this product or product name] to ultrasonic unit per manufacturer's instructions. Immerse instruments in solution and activate ultrasonic unit for the indicated amount of time. Remove and rinse instruments. Follow with appropriate disinfection or sterilization process. Discard solution after each use.]

[For use as a manual cleaner: Thoroughly rinse instruments under running water to remove visible gross debris. Place instruments in a container and cover with [this product or product name]. Scrub instruments while submerged for 30 seconds using a stiff bristle brush until visibly clean. Remove and rinse instruments. Follow with appropriate disinfection or sterilization process. Discard solution after each use.]

[For cleaning hair clippers and electric shears: While clipper/electric shear is running, hold it in the downward position and spray [this product or product name] to thoroughly wet the blades. Allow to remain wet for one minute. Avoid spraying on the clipper case or dripping into the clipper housing. Rinse clipper/electric shears and follow with appropriate lubricating process.]

[For cleaning salon implements and shears: Spray with [this product or product name] to thoroughly wet the implement/shear. Allow to remain wet for one minute. Wipe away visible debris using a soft bristle brush or cloth. Rinse implement/shear and follow with appropriate lubricating process.]

# \*VIRUCIDAL [EFFICACY] [AGAINST THE FOLLOWING ORGANISMS] [IN ONE [1] MINUTE]:

[This product or product name] is *or* are an effective virucide on hard, non-porous surfaces, in the presence of an organic load, against *Adenovirus type 5* [ATCC VR-5], *Avian Influenza A Virus* [ATCC VR-798], *Cytomegalovirus* [ATCC VR-953], *Enterovirus EV-D68* [ATCC VR-1826], *Hepatitis B Virus*, *Hepatitis C Virus*, *Herpes Simplex Virus Type 1* [ATCC VR-539], *Human Coronavirus* [ATCC VR-1558], *Human Immunodeficiency Virus* [HIV-1] [AIDS], *Influenza Virus type A*<sup>2</sup> [ATCC VR-544], *Influenza B* [ATCC VR-102], *Norovirus*, *Poliovirus serotype 1* [PV-1] [ATCC VR-1562], *Respiratory Syncytial Virus* [ATCC VR-26], *Rhinovirus* [ATCC VR-340], *Rotavirus Strain WA* [ATCC VR-2018], [and] *Vaccinia virus* [ATCC VR-119], when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.

[The following information specifically applicable to HIV-1, HBV, and HBC, may appear grouped together anywhere on the label and is required if human healthcare sites including but not limited to hospitals, clinics, physicians' offices, and/or dental offices/operatories are included on the label]

KILLS HIV-1, HBV and HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings [Hospitals, Nursing Homes] or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 [HIV-1] [associated with AIDS], Hepatitis B Virus [HBV], and Hepatitis C Virus [HCV]

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV, and HCV FOR SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS.

**PERSONAL PROTECTION:** When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings.

<u>CLEANING PROCEDURES</u>: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of [this product or product name].

**CONTACT TIME:** Allow surface to remain wet for 1 full minute.

<u>DISPOSAL OF INFECTIOUS MATERIALS</u>: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

These Influenza Related Optional Statements May Appear Elsewhere on the Label

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. This product [Product Name] is a broad-spectrum hard surface disinfectant that has been shown to be effective against [Influenza A virus tested and listed on the label] and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 [formerly called swine flu].
- This product [Product Name] has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.
- This product [Product Name] has demonstrated effectiveness against [Influenza A virus tested and listed on the label] and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 [formerly called swine flu].
- Kills Pandemic 2009 H1N1 Influenza A virus [formerly called swine flu].
- Kills Pandemic 2009 H1N1 Influenza A virus

#### [BACTERIAL] [EFFICACY] [AGAINST THE FOLLOWING ORGANISMS] [IN ONE [1] MINUTE]:

#### DRUG RESISTANT AND MULTI-DRUG RESISTANT BACTERIA

[This product or product name] is an effective disinfectant on hard non-porous surfaces, in the presence of an organic load, against *Acinetobacter baumanni* — Multi-Drug resistant [MDR] [ATCC 19606], *Carbapenem resistant Enterobacter cloacae* (CRE) (KPC) [Multi-Drug resistant] [MDR] [ATCC BAA-2341], *Carbapenem resistant Enterobacter cloacae* (CRE) (New Delhi) [Multi-Drug resistant] [MDR] [ATCC BAA-2468], *Enterococcus faecium* — Vancomycin resistant (VRE) [ATCC 51559], *Escherichia coli* — ESBL Producing [Multi-Drug resistant] [MDR] [ATCC BAA-196], *Klebsiella pneumoniae* — ESBL Producing [Multi-Drug resistant] [MDR] [ATCC 700603], *Staphylococcus aureus* — Methicillin resistant (MRSA) [ATCC 33591], *Staphylococcus aureus* — Vancomycin resistant (VRSA) [ATCC NR-49120], [and] *Staphylococcus aureus Panel* — Vancomycin intermediate (VISA) [CDC AR-Bank 0216], when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.

#### **BACTERIA**

[This product or product name] is an effective disinfectant on hard non-porous surfaces, in the presence of an organic load, against *Bordatella pertussis* [ATCC 12743], *Burkholderia cepacia* [ATCC 25416], *Campylobacter jejuni* [ATCC 29428], *Enterobacter aerogenes* [ATCC 13048], *Escherichia coli* [E. coli] O157:H7 [ATCC 35150], *Klebsiella pneumonia* [ATCC 4352], *Legionella pneumoniae* [ATCC 35150], *Listeria monocytogenes* [ATCC 984], *Proteus vulgaris* [ATCC 9920], *Pseudomonas aeruginosa* [ATCC 15442], *Salmonella enterica* [Salmonella] [ATCC 10708], *Shigella dysenteriae* [ATCC 13313], *Staphylococcus aureus* [ATCC 6538], *Streptococcus pyogenes* [Strep] [ATCC 19615], [and] *Streptococcus pneumoniae* [ATCC 6305], when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.

#### **TUBERCULOCIDAL:**

[This product or product name] is an effective disinfectant on hard non-porous surfaces, in the presence of an organic load, against *Mycobacterium bovis* [ATCC 35743], when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.

#### **FUNGICIDAL:**

[This product or product name] is an effective fungicide on hard non-porous surfaces against *Trichophyton mentagrophytes* [ATCC 9533] [causative agent of Athlete's Foot Fungus] [a cause of ringworm] [a cause of ringworm of the foot], when used as directed [in bathrooms, shower stalls, locker rooms, exercise facilities or other surfaces commonly contacted by bare feet], and *Candida albicans* [ATCC 10231], when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.

The Following Optional Claims Are Intended For Veterinary or Other Animal Related Facilities

### **ANIMAL PATHOGENS:**

[This product or product name] is an effective disinfectant on hard non-porous surfaces against Avian Influenza A Virus [ATCC VR-798], Bordatella bronchiseptica [ATCC 4617], Bovine Diarrhea Virus [(BVDV)], Canine distemper Virus [ATCC VR-1587], Canine parvovirus [ATCC VR-953], Duck Hepatitis B Virus [(BVDV)], Feline calicivirus, and Feline leukemia Virus [ATCC VR-1373].

EFFICACY TESTS HAVE DEMONSTRATED THAT [THIS PRODUCT OR PRODUCT NAME] IS AN EFFECTIVE, VIRUCIDE, BACTERICIDE, TUBERCULOCIDE AND FUNGICIDE IN THE PRESENCE OF [5%] ORGANIC SOIL.

As An Alternative the Following Consolidated Format for Stating Pathogen Claims May Be Used

[This product or product name] is or are an effective virucide, bactericide, tuberculocide and fungicide on hard non-porous surfaces, in the presence of an organic load, against Adenovirus type 5 [ATCC VR-5], Avian Influenza A Virus [ATCC VR-798], [Canine distemper Virus [ATCC VR-1587], Canine parvovirus [ATCC VR-953]], Cytomegalovirus [ATCC VR-953], Enterovirus EV-D68 [ATCC VR-1826], [Feline calicivirus, and Feline leukemia Virus [ATCC VR-1373]], Hepatitis B Virus, Hepatitis C Virus, Herpes Simplex Virus Type 1 [ATCC VR-539], Human Coronavirus [ATCC VR-1558], Human Immunodeficiency Virus [HIV-1] [AIDS], Influenza Virus type A<sub>2</sub> [ATCC VR-544], Influenza B [ATCC VR-102], Norovirus, Poliovirus serotype 1 [PV-1] [ATCC VR-1562], Respiratory Syncytial Virus [ATCC VR-26], Rhinovirus [ATCC VR-340], Rotavirus Strain WA [ATCC VR-2018], Vaccinia virus [ATCC VR-119], [Bordatella bronchiseptica [ATCC 4617]], Bordatella pertussis [ATCC 12743], Burkholderia cepacia [ATCC 25416], Campylobacter jejuni [ATCC 29428], Enterobacter aerogenes [ATCC 13048], Escherichia coli [E. coli] O157:H7 [ATCC 35150], Klebsiella pneumonia [ATCC 4352], Legionella pneumoniae [ATCC 35150], Listeria monocytogenes [ATCC 984], Proteus vulgaris [ATCC 9920], Pseudomonas aeruginosa [ATCC 15442], Salmonella enterica [Salmonella] [ATCC 10708], Shigella dysenteriae [ATCC 13313], Staphylococcus aureus [ATCC 6538], Streptococcus pyogenes [Strep] [ATCC 19615], Streptococcus pneumoniae [ATCC 6305], Mycobacterium bovis [ATCC 35743], Trichophyton mentagrophytes [ATCC 9533]; and Candida albicans [ATCC 10231], when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.

The Following Listing of Pathogens, By Category, May Appear on the Front Label Panel or Elsewhere on the Label, In Any Order, Together or Divided, When Used in Conjunction With the Above Listing of All Pathogens Grouped Together, Elsewhere on the Label

#### BACTERICIDAL

Bordatella pertussis
Burkholderia cepacian
Campylobacter jejuni
Enterobacter aerogenes
Escherichia coli O157 [E. coli]
Klebsiella pneumonia
Legionella pneumoniae
Listeria monocytogenes
Proteus vulgaris
Pseudomonas aeruginosa
Salmonella enterica
Shigella dysenteriae
Staphylococcus aureus [Staph]
Streptococcus pneumoniae [Strep]
Streptococcus pneumoniae [Strep]

#### +VIRUCIDAL

+Adenovirus type 5 +Avian Influenza A Virus +Cytomegalovirus +Enterovirus EV-D68 +Hepatitis B Virus [HBV] +Hepatitis C Virus [HBC] +Herpes Simplex Virus Type 1 +Human Coronavirus +Human Immunodeficiency Virus [HIV-1] [AIDS] +Influenza Virus type A<sub>2</sub> [Flu] +Influenza B [Flu] +Norovirus +Poliovirus +Respiratory Syncytial Virus [RSV] +Rhinovirus +Rotavirus Strain WA +Vaccinia virus

#### **TUBERCULOCIDAL**

Mycobacterium bovis

#### **FUNGICIDAL**

Trichophyton mentagrophytes [Athletes Foot fungus] Candida albicans The Following Language is Intended to be Used in Accordance With the US EPA "Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels"

This product meets the criteria for use against the following categories of emerging viral pathogens when used in accordance with the use directions for

Poliovirus type 1 (ATCC VR-1562) and Rhinovirus (ATCC VR-340):

- -Enveloped Viruses
- -Large Non-Enveloped Viruses
- -Small Non-Enveloped Viruses

Per EPA "Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels".

Statements intended for technical literature, "1-800" consumer information services, social media sites and company websites (non-label related). Information is NOT to appear on marketed product labels. One or both statements below may be used.)

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus, which must be a small non-enveloped, large non- enveloped, or enveloped virus] on [eligible surface type(s)]. Therefore, [product name] can be used against [name of emerging virus, which must be a small non-enveloped, large non-enveloped, and/or enveloped virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, non-porous surfaces]. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

or

[Name of illness/outbreak] is caused by [name of emerging virus, which must be a small nonenveloped, large non-enveloped, and/or enveloped virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus, which must be a small nonenveloped, large non-enveloped, and/or enveloped virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.

#### PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

**CAUTION**: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

#### **FIRST AID**

**IF IN EYES**: Hold eyes open and rinse slowly and gently with water for 15–20 minutes. Remove contact lenses if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center [NPIC] at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time [NPIC Web site: www.npic.orst.edu].

#### PHYSICAL OR CHEMICAL HAZARDS:

Flammable. Keep away from heat or open flame.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Always store this product and all pesticides in the original container. If a leaky container must be contained within another, mark the outer container to identify the contents. Protect from extreme heat or cold.

PESTICIDE DISPOSAL: Waste resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

#### For nonrefillable containers

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or discard empty container in trash.

#### For refillable containers

CONTAINER DISPOSAL: Refillable container. Refill plastic canister with this brand of pesticide product only. Do not reuse this container for any other purpose. Offer plastic container for recycling if available, or discard in trash.

Statement Regarding Surface Compatibility Which May Appear Anywhere on the Label

[This product or product name] will not harm most surfaces: including stainless steel, aluminum, other hard and soft metals, quartz or other solid man-made counter top materials, most plastics, fiberglass, vinyl, nylon, and other upholstery materials used in a [medical] [or] [veterinary] [or] [dental] environment, and most painted surfaces. For plastic and painted surfaces, spot test on an inconspicuous area before use. Not recommended for use on acrylic plastics or coated optical surfaces. Do not use on unpainted wood, or leather. Not for use on people or pets.

## The Following Additional Marketing Claims Are Optional and May Appear Anywhere on the Label

- disinfects [odor causing] [common] [household] [bathroom] bacteria
- · maximum cleaning, minimum effort
- easy to [carry] [use] [container] [dispensing system]
- for all [household] [institutional] hard, nonporous surfaces
- great for clean-up at school, daycare or community center
- uses [x]% less plastic than other [bottles] [containers] [in the market]
- uses [x]% less packaging than similar products
- uses [x]% recycled materials in the packaging
- packaging made from [x]% renewable resources

The Following Optional Warranty and Disclaimer Statement[s] May Appear Anywhere on the Label

### LIMITED WARRANTY AND DISCLAIMER NOTICE:

The manufacturer of this product and/or it's affiliates and distributors warrant that this product conforms to the chemical description on this label and is reasonably fit for the purposes referred to in the Directions For Use and elsewhere on this label. Buyer assumes all risks of use and handling which is a variance in any way with the directions herein. The manufacturer makes no other express or implied warranty of fitness or merchantability. In no case shall the manufacturer or the seller of this product be liable for consequential, special or indirect damages resulting from the use or handling of this product. The manufacturer, distributor, and seller, and the buyer and user of this product acknowledge and accept the foregoing Limited Warranty and Disclaimer which may be varied only by agreement in writing signed by a duly authorized representative of the manufacturer.

or

No warranty, either expressed or implied, is given to the usage contrary to the instructions given herein.

## The Following Table, or Portions Thereof, May Appear On the Printed Product Label and May Appear in Associated Marketing Materials

This Product [product name] Kills the Following Pathogens in One Minute			
		Organic	
Pathogen	ATCC Number	Load	Kill Time
Acinetobacter baumannii	19606	5%	1 minute
Bordatella bronchiseptica	4617	5%	1 minute
Bordatella pertussis	12743	5%	1 minute
Burkholderia cepacia	25416	5%	1 minute
Campylobacter jejuni	29428	5%	1 minute
Enterobacter aerogenes	13048	5%	1 minute
Enterobacter cloacae (CRE) multi-drug resistant	BAA-2341	5%	1 minute
Enterobacter cloacae (CRE) (New Delhi) multi-drug resistant	BAA-2468	5%	1 minute
Escherichia coli O157:H7 [E. coli]	35150	5%	1 minute
Escherichia coli (ESBL) TEM-10 multi-drug resistant	BAA-196	5%	1 minute
Klebsiella pneumoniae	4352	5%	1 minute
Klebsiella pneumoniae (ESBL) SHV-18 multi-drug resistant	700603	5%	1 minute
Legionella pneumophila	33153	5%	1 minute
Listeria monocytogenes	984	5%	1 minute
Methicillin resistant Staphylococcus aureus [MRSA]	33591	5%	1 minute
Proteus vulgaris	9920	5%	1 minute
Pseudomonas aeruginosa	15442	5%	1 minute
Salmonella enterica	10708	5%	1 minute
Shigella dysenteriae	13313	5%	1 minute
Staphylococcus aureus [Staph]	6538	5%	1 minute
Streptococcus pneumoniae	6305	5%	1 minute
Streptococcus pyogenes [Strep]	19615	5%	1 minute
Vancomycin Intermediate Staphylococcus aureus Panel [VISA]	CDC AR-Bank 0216	5%	1 minute
Vancomycin Resistant Enterococcus faecium [VRE]	51559	5%	1 minute
Vancomycin Resistant Staphylococcus aureus [VRSA]	NR-49120	5%	1 minute
Mycobacterium bovis [Tuberculosis]	35743	5%	1 minute
Candida albicans	10231	5%	1 minute
Trichophyton mentagrophytes [Athletes Foot fungus]	9533	5%	1 minute
Adenovirus	VR-5	5%	1 minute
Avian Influenza	VR-798	5%	1 minute
Canine distemper virus	VR-1587	5%	1 minute
Canine parvovirus	VR-953	5%	1 minute
Coronavirus	VR-1558	5%	1 minute
Cytomegalovirus	VR-953	5%	1 minute
Enterovirus EV-D68	VR-1826	5%	1 minute
Feline leukemia virus	VR-1373	5%	1 minute
Hepatitis B	n/a	5%	1 minute
Hepatitis C	n/a	10%	1 minute
Herpes Simplex virus type 1	VR-539	5%	1 minute
Human Immunodeficiency virus [HIV-1] [AIDS]	n/a	10%	
			1 minute
Influenza virus type A2 [Flu] Influenza virus type B [Flu]	VR-544	5% 5%	1 minute
,, , , ,	VR-102		1 minute
Norovirus	n/a	5%	1 minute
Poliovirus	VR-1562	5%	1 minute
Respiratory Syncytial virus [RSV]	VR-26	5%	1 minute
Rhinovirus	VR-340	5%	1 minute
Rotavirus, Strain WA	n/a	5%	1 minute
Vaccinia virus	VR-119	5%	1 minute

Brackets [] Denote Optional Language





